



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,310	05/31/2001	Robert Ainsworth	3764.P180	4544
8791	7590	11/29/2005	EXAMINER	
BLAKELY SOKOLOFF TAYLOR & ZAFMAN 12400 WILSHIRE BOULEVARD SEVENTH FLOOR LOS ANGELES, CA 90025-1030			JUNG, WILLIAM C	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,310

Applicant(s)

AINSWORTH ET AL.

Examiner

William Jung

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-21, 26, 27, 32-35 and 44-46 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-21, 26, 27, 32-35 and 44-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed August 29, 2005 have been fully considered but they are not persuasive.

Examiner respectfully disagrees with the applicant after further consideration of the amendment and response. The added limitation to the independent claims 1, 15, 26, 32, 34, and 44 where "coil-like enclosure" replaces the sheath over the optical fiber, does not distinguish over McGee et al, along with argument that Mc Gee et al do not disclose the coil like enclosure. Mc Gee et al disclose the same limitation on col. 11, line 60 – col. 12, line 9, where the electrode 30 comprises a conductive material and spaced apart lengths of closely wound, spiral coils wrapped about the sleeve 32. The arguments for the dependent claims are based on the applicant's argument on independent claims. Therefore, the amendment and the argument are ineffective and the Examiner maintains the rejection from the previous office action. The rejection below is same as in previous office action with addition of coil-like enclosure stated above. Since the rejection is based on same references as the previous office action, the action is made FINAL.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3737

3. Claims 1, 2, 5, 7-9, 11-13, 15-19, 21, 26, 32, 34, and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by *McGee et al* (US 5,752,518).

Claims 1, 15, 26, and 44: McGee et al anticipate all claimed elements in claims 1, 15, 22, 26, 28, 40, and 44: McGee et al disclose an intravascular catheter 10 comprising structure 20 to perform diagnostic imaging and therapeutical treatment with sheathed optical fibers 44 disposed through the intravascular catheter. In addition, a sheath is slidably disposed over the catheter shaft and an intraluminal gap extending longitudinally along the elongated member.

Furthermore, the control of the intravascular catheter is achieved with guidewire (col. 5, line 30-34). The imaging using either ultrasound transducer or fiber optic assembly can be used before and after the treatment to assess treatment area (col. 1, lines 44-67; col. 3, line 53 – col. 4, line 39; col. 4, line 62 – col. 5, line 10). In addition, McGee et al intravascular catheter has expandable portion 64 (col. 7, lines 53-60). Further more, McGee et al disclose the same limitation on col. 11, line 60 – col. 12, line 9, where the electrode 30 comprises a conductive material and spaced apart lengths of closely wound, spiral coils wrapped about the sleeve 32.

Claims 32 and 34: McGee et al further disclose in figure 6 where receiver & processor 57 processes the data and display on display unit 59.

Claims 2 and 19: McGee et al shows in figure 4A, where the optical fiber 20 is exposed within a vasculature of a patient.

Claims 5, 8, 9, 12, 13, 16, 18, and 46: McGee et al disclose that the inflatable portion 64 is a balloon catheter disposed about a tubular inner member having a lumen to receive the optical fiber 34 (col. 7, lines 52-61). The inflatable balloon can be applied in procedure such as angioplasty, stenting and restenting (col. 3, line 62 – col. 4, line 9).

Claims 7, 11, 17, and 45: I figures 1 and 5A McGee et al shows that the optical fiber 34 is coupled to the tubular inner member and is movable within the lumen. In addition, figure 5A shows that the optical fiber is substantially parallel to the tubular member.

Claims 12 and 18: As described above, McGee et al disclose the catheter where the lumen is consisting of guidewire, inflatable balloon, radiation source, atherectomy, laparoscopy, and drug delivery (col. 3, line 62 – col. 4, lines 9; col. 5, lines 40-45).

Claim 21: McGee et al disclose that the optical fiber and lumen may include radiopaque materials (col. 5, lines 40-45).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3, 4, 10, 14, 20, 33, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over *McGee et al* as applied to claims 1, 2, 5, 8, 9, 11-13, 15, 19, 27, 32, and 34 above, and further in view of *Morantte, Jr.* (US 4,587,972).

McGee et al substantially disclose all claimed features in claims 3, 4, 10, 14, 20, 33, and 35. However, McGee et al do not specifically disclose a measurement of vessel and blood characteristic such as hemodynamic characteristics. In *Morantte, Jr.*, an intravascular catheter is used to diagnosis and treat blood vessel by measuring hemodynamic characteristics of the blood vessel using optical source or laser energy to assess the level of treatment or therapy required (col. 4, line 42 – col. 5, lines 17). Therefore, it would have been obvious to one having an

ordinary skill in the art at the time the invention was made to apply the teachings of Morantte, Jr.'s hemodynamic characteristic measurement to assess therapy guideline using optics or laser to improve McGee et al's apparatus where it includes therapy assessment by imaging.

Conclusion

6. This is a continuation of applicant's earlier Application No. 09/872,310. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

Art Unit: 3737

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

WJ

November 25, 2005

Brian Casler
SPB 3737